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A P3G Generic Access Agreement for Population Genomic Studies

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The Public Population Project in Genomics and Society (P3G) is a not-for-profit consortium that provides the international research community with access to the expertise, resources and innovative tools for the harmonization of health and social sciences research. (www.p3gconsortium.org) This "Generic Access Agreement" is a tool developed for use by population genomic studies (also often called biobanks or resources). Over the past decade, in anticipation of expanding demand for access by researchers and industry, large population studies collecting DNA samples worldwide have been developing access principles and policies to ensure ethical and legal access procedures to their resource that respect participant consent (see Table 1). These access policies are now being operationalized into agreements that clearly stipulate the obligations of researchers and institutions who wish to access these resources. The access agreement is typically the final step in the access request process, following the submission and successful review of an application for access.[1]

This P3G Generic Access Agreement attempts to address both the sharing of data and the sharing of materials (i.e. biospecimens). All studies named in Table 1 provide data, while some may additionally allow access to the biological samples themselves, under certain conditions. While many aspects of access apply uniformly between data and materials, there are certain considerations unique to materials, such as their limited and depletable nature. Our proposed Agreement aims to foster some level of uniformity of access by addressing both data and materials together.

Access agreements must be drafted clearly, not only so that researchers and their institutions are aware of their obligations, but also in order that "the border between acceptable and unacceptable conduct be clearly delineated and predictable…"[2] Explicit sanctions are important in order to respond effectively to any breach. These sanctions must be balanced: harsh enough to deter abuse by researchers and yet not discourage access.

We have surveyed available literature, policies, and access agreements in an attempt to identify access norms. These norms have been captured by the P3G "Generic Access Agreement." Its utility, however, extends beyond suggesting best practices, as it also aims to enhance international harmonization of access procedures. Researchers should not encounter a completely different access procedure each time they apply for access to a study. Mindful of national and cultural heterogeneity, the Agreement seeks to promote scientific knowledge as a common good that should be shared, with appropriate protections in place. The adoption of this unique tool will hopefully improve transparency and interoperability in the sharing of data and samples.

It is problematic for population studies to simply rely on existing agreements. First, significant heterogeneity exists between studies, and existing access agreements often reflect

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peculiarities. The “Generic Access Agreement” seeks to harmonize the core conditions that should be considered by all population studies. Second, existing agreements are often limited to data, and rarely address the use of and access to samples. Third, existing access agreements tend to be conceived in highly legalistic terms. This drafting approach is problematic because it lacks the clarity needed to communicate clear and understandable expectations to researchers as to their commitments. The P3G Generic Access Agreement offers not only a principled analysis of the content of access agreements, it also provides explicit clauses to promote comprehensibility among researchers.

It is essential that these agreements are not developed in isolation. Harmonization, at the current implementation stage of population studies, will reinforce international data and sample sharing norms, promote equitable procedures, and improve researcher familiarity with simplified access procedures. Ultimately, some agreement on core bioethical principles[3] and the procedures accompanying them will foster an equitable and transparent playing field across population studies and foster their translation into genomic medicine.

The P3G “Generic Access Agreement” has drawn on a variety of sources. A selection of existing data or material access agreements among P3G members was reviewed to determine common elements. Access-related documents from population studies – such as publication policies, intellectual property policies and consent forms – were also reviewed to ensure coherent integration. General principles were drawn from existing P3G resources developed to encourage harmonization in access.[4,5,6,7] The sources reviewed are listed in Table 1.

From the results of our review, a provisional generic access agreement was drafted by the legal team at the Centre of Genomics and Policy of McGill University. The draft agreement was then circulated for two iterations of comments and revisions among the P3G International Steering Committee.[8] The resulting version of the agreement was then discussed and approved via the consensus of both the International Steering Committee and the Board of the P3G.[9]

A few drafting principles were adopted in the preparation of this document: brevity; clear and simple language (as such agreements will often be read by scientists and administrators with limited legal training); and limiting of the template to essential elements so as to encourage uniform treatment of access applications, reduce time for negotiation between the study and researchers, and allow customization for local needs and laws.

Certain issues were encountered in the drafting of this document. There was uncertainty concerning the commensurability of procedures for access to data and access to samples. Initially, the team developed a list of “special considerations for samples.” While samples require unique treatment for their quality, security, liability, and disposal upon termination, we found that they could largely be integrated under general conditions used in the access agreement.

Significant discussion also went into the Intellectual Property terms. Our definition of “Invention” was drawn from the European Parliament and Council’s Directive on biotechnological inventions.[10] The discussion reflected the tension between incentivizing research by allowing limited patent protection of inventions, and promoting the valorization of the resource by allowing future research to build on the findings of past research. The final solution is to protect the potential for downstream patentability while reserving a robust, open license for future use and sublicense. Thus, protection for downstream inventions is explicitly recognized, with reference to international directives that were judged to offer the best balance of the interests. Finally, certain types of conditions mentioned in existing access agreements were not included. The most common reasons were

that these conditions were overly technical and legalistic, or too specific to a certain type of study to merit inclusion in a generic access agreement.

The success of population studies will depend on their ability to adequately balance promotion and regulation of access. Research will suffer if the conditions of access are too strict; participants will suffer if they are too liberal. The P3G Generic Access Agreement aims to strike this essential balance, to ensure equitable and clear conditions of access for population studies. The Agreement's successful adoption by the member institutions of P3G will help to establish an international standard for access to population studies. Their effective translation into population health will hopefully be enhanced and promoted.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

The International Steering Committee of P3G dedicates this article to the late David Cox - a co-author, visionary scientist and friend.

REFERENCES

1. UK Biobank. Access Procedures: Application and Review Procedures for Access to the UK Biobank Resource. Nov.2011 v 1.0
2. Joly Y, et al. Genomic databases access agreements: legal validity and possible sanctions. Human Genetics. 2011; 130(3):441–449. [PubMed: 21706183]
3. Knoppers BM, Harris JR, Tassé AM, Budin-Ljøsne I, Kaye J, Deschênes M, Ma'n H Zawati. Towards a data sharing code of conduct for international genomic research. Genome Med. 2011; 3:1–4. [PubMed: 21255381]
4. Fortin S, Pathmasiri S, Grintuch R, Deschênes M. 'Access arrangements' for biobanks: A fine line between facilitating and hindering collaboration. Public Health Genomics. 2011; 14(2):104–114. [PubMed: 20689244]
5. Pathmasiri, S.; Knoppers, BM. (P3G Policymaking Core). Material and data access agreements: core elements. 2008. online: P3G http://www.p3gobservatory.org/repository/ethics.htm
6. Susan, Wallace. (P3G Policymaking Core). P3G sample and data access: core elements. 2009. online: P3G http://www.p3gobservatory.org/repository/ethics.htm
7. European Commission. Biobanks for Europe, A Challenge for Governance. European Union; Luxembourg: 2012.
8. Current Members of the P3G International Steering Committee. online: http://www.p3g.org/about-p3g/international-steering-committee
9. P3G Board meeting on September 14th, 2012.
10. European Parliament and Council. Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions.

Table 1
Existing Agreements, Related Policies and Guidelines Reviewed

Organisation	Document	Version/Date
Avon Longitudinal Study of Parents and Children	*Management and Policy*	(v 3.0, Dec 2011)
Avon Longitudinal Study of Parents and Children	*Access Policy and Material Transfer Agreement*	(v 4.1, Oct 2012)
CARTaGENE	*Access Agreement*	
Canadian Partnership for Tomorrow Project	*Data Access Policy*	(March 2012)
Electronic Medical Records and Genomics Network	*Data Use Agreement*	(v4.3, March 2010)
Generation Scotland	*Management, Access and Publications Policy*	
International Cancer Genome Consortium	*Data Access Agreement Goals,*	(1 August 2009)
International Cancer Genome Consortium	*Structure, Policies & Guidelines*	(April 2008)
National Cancer Research Institute	*Samples and Data for Research: Template for Access Policy Development*	(June 2009)
P3G Ethics and Policymaking Core	*Material and Data Access Agreements: Core Elements*	(2008)
P3G Ethics and Policymaking Core	*Model Consent Form*	(Feb 2011)
The Cancer Genome Atlas	*Data Use Certification Agreement*	(1 March 2010)
The Cancer Genome Atlas	*Human Subjects Protection and Data Access Policies*	
UK Biobank	*Access Procedures: Application and Review*	(v 1.0, 8 Nov 2011)
UK Biobank	*Material Transfer Agreement for Data and/or Samples*	(8 Nov 2011)
The Wellcome Trust Case-Control Consortium	*Data Access Agreement*	(v 18, June 2010)
The Wellcome Trust Case-Control Consortium	*Access Policy: Access to Genotype Data*	(v 1, July 2009)